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MICHAEL L. DUNN
SIMPSON & SIMPSON, PLLC
5555 MAIN STREET
WILLIAMSVILLE, NY 14221

| EXAMINER | |
|---|---|
| BERRIOS, JENNIFER A | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/567,631 | BLUME ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer A. Berríos | 1619 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *13-36* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's election with traverse of species (alcohol: glycerin; lipid conjugate solvent: jojoba oil; nicotinic compound: nicotinic acid; and lipid conjugate: galactocerebrosides) in the reply filed on 4/16/2009 is acknowledged. The traversal is on the ground(s) that Examiner is mixing U.S and PCT practice, by requiring an election of species. Argument is also made that examiner has not proven lack of unity of invention. This is not found persuasive because Examiner has determined that there is in fact a lack of unity of invention.

2. Claim 13 lack unity of invention for the following reasons: Claim 13 recites a special technical feature of a cosmetic composition comprising a lipid conjugate, consisting of sphingolipids, galactolipids and mixtures thereof, and a fluorocarbon. This special technical feature lacks unity in view of Unger (US 5,705,187, issued: 1/6/1998) and Felke et al (WO 95/20945, pub date: 2/16/1995), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998), as described in the 103 rejection below. As such, unity between claims 13-36 is broken. A species election is further requested to define the lipid conjugate, as the species lack a special technical feature amongst them, as demonstrated in the Restriction Requirement mailed on 12/19/2008 and the 103 rejections listed below.

3. Claim 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/16/2009.

The requirement is still deemed proper and is therefore made **FINAL**.

### *Priority*

4. This application is a 371 of PCT/EP04/51702 filed on 8/4/2004.

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) of application 103-36-841.8 filed on 8/11/2003 in Germany.

6. All examined claims will receive a priority date of 8/4/2004.

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 33-36 recites the limitation "the cosmetic composition of claim 13 where the composition contains 1,2-propylene glycol, glycerin, sphinogolipid-oil/wax solution, PEG 75-shea butter, perfluorodecalin and water" in claim 33-36. There is insufficient antecedent basis for this limitation in the claim. The composition of claim 13 does not contain any type of alcohol, PEG-75 Shea Butter glyceride, or water.

### *Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 13-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,705,187, issued: 1/6/1998) and Felke et al (WO 95/20945, pub date: 2/16/1995), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998).

Unger teaches a composition comprising in an aqueous carrier, a lipid and a material which is capable of stabilizing the composition. The composition can take the

form of vesicular composition, such as micelles and liposome's (Abstract) Stabilizing materials can be hydrophilic polymers, such as poly(ethyleneglycol) (PEG), poly(vinylalcohol) and more (Column 18, lines 8-11).

Regarding claims 13 and 20, Unger teaches that a variety of lipid compounds can be employed, such as sphingolipids, glycolipids, phospholipids and glycosphingolipids among others (Column 8, lines 45-57). A gas, such as inert gas is incorporated into the lipid composition and provides the composition with enhances reflectivity, particularly in vesicular compositions (Column 15, lines 5-10). In certain embodiments, the gas is a perfluorocarbon combined with a liquid perfluorocarbon, such as perfluorodecalin, perfluoroheptane, PFOB and perfluorododecalin among others (Column 15, lines 28-32). With respect to in vivo applications the formulations of the present invention can de administered orally, by parental administration, topically, dermal ocular, rectal, nasal and more (Column 19, lines 14-25). The composition can further comprise bioactive agents, such as pharmaceuticals, drugs, vitamins, peptides, nucleotides. Although Unger doesn't teach the composition to be in a cosmetic, the term "cosmetic composition" is defined by the instant specification to also encompass pharmaceutical compositions.

Regarding claims 17-19, Unger teaches that preferred vesicles are formulated from lipids. The lipids may be in the form of a monolayer or bilayer. The lipid vesicles include entities referred to as bubbles, micelles, liposomes, spheres and the like (Column 5-lines 65-67 to Column 9-lines 1-8). Preferably the liposomes are small, that is less than 100 nanometers. Although nanoparticle isn't defined by the prior art, nor by

the instant specification, Merriam-Webster's dictionary defines a nanoparticle to be “a microscopic particle whose size is measured is nanometers,” as such the liposome’s of Unger are considered to be nanoparticles. (Column 14, lines 23-25).

Unger fails to teach the quantities in which the lipids and the fluocarbon’s are found in the composition and fails to teach the lipid conjugate to be galactocerebrosides (the elected species). Felke teaches a functional oxygen-containing preparation comprising phospholipids and one or more oxygen-loaded fluorocarbons. The fluorocarbons are present in amounts ranging from .2-100%w/v and the lipids are present in amounts ranging from 30-99%wt. This preparation may be used for the administration of nutrients, active ingredients and protectants to the skin, as cosmetics, and the compounds have a high oxygen content (Abstract).

Regarding claims, 14-15, Schmidt teaches an active ingredient system present in products such as sprays, gels, creams or salves. The active ingredients are used in medicine, pharmaceuticals and cosmetics (Abstract). A desired active ingredient would comprise a lipid transfer protein capable of transferring glycolipids and a lipid source comprising glucolipids and the skin lipids in the form of an emulsion to be applied to the skin. An example of a favorable used lipid component is a glycolipid which exits in natural skin structures and which normally builds the evaporation barrier. Gluco- and galactocerebrosides are preferred glycolipids which can be isolated out of natural products or are commercially available (Column 8, lines 1-10, Claims 8-9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Unger, Felke and Schmidt to

arrive at the instant invention. One of skill in the art would have been motivated to utilize the pharmaceutical composition taught by Unger and utilize the galactocerebrosides taught by Schmidt as the lipid vesicles, since these naturally build an evaporation barrier, which would prove useful for topical pharmaceutical applications. One would have also been motivated to utilize the lipids and fluorocarbon percentages taught by Felke, since Felke teaches that those percentages in a preparation are useful for the administration of nutrients, active agents and protectants to the skin (topical application) and have a high oxygen content. One of skill in the art would expect reasonable success because Felke and Unger teach pharmaceutical/cosmetic composition that comprise lipids and fluorocarbons and Schmidt teaches a specific glycolipids which as a natural property useful in cosmetics, an evaporation barrier.

14. Claims 13, 21-23, 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,705,187, issued: 1/6/1998) and Felke et al (WO 95/20945, pub date: 2/16/1995), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998) as applied to claims 13-15 and 17-20 above, and further in view of Kawahara et al (US 2002/0037291, pub date: 3/28/2002).

Unger/Felke/Schmidt teach all the limitations of claim 13, but fails to teach the limitations further recited by claims 21-23, 28-30 and 32.

Kawahara teaches a novel glycosphingolipid that exhibits a moisturizing effect and immuno-enhancing activity (Abstract). It also teaches that there is no limitation on

the forms of the cosmetic or pharmaceutical composition containing the glycosphingolipid, So that many forms of solid, liquid, paste, jelly and powder are allowable (Pg 3 [0036]).

Regarding claims 28-30, Kawahara provides various examples of different types of compositions ranging from emollient cream, lipstick, cheek color, eyebrow color, hair rinse, hand cream and more that include an active ingredient (glycosphingolipids), in amounts ranging from 2-20% in combination with other ingredients. In cosmetic preparations, such as demonstrated by the examples containing tables 8, 13, 18, 20 and 19 (Pg 7-9) the composition can comprise alcohols specifically glycerin or a combination of glycerin and propylene glycol (also referred to as 1,2-propylene glycol). Glycerin can be found in amounts of 2%, 4%, 20%, 2.5% and 1%, thus ranging from 1-20%. And propylene glycol is present in 10% by weight of the composition.

Regarding claims 21-23, Kawahara further teaches that suitable fats and oils can be added for use in cosmetic and pharmaceutical preparations (Pg 3 [0040]). Examples include beeswax, carnauba wax, and liquid paraffin among others. Table 11 shows the use of 2% of jojoba oil (elected species) in the composition. Tables 12 and 18 show the use of Beeswax and Carnauba Wax in amounts of 5% and liquid paraffin in an amount of 10%. As seen by the examples jojoba oil, beeswax, carnauba wax and liquid paraffin are the preferred oils to be used in the cosmetic compositions and can range from amounts of 2-10%. So it would have been obvious to one of skill in the art to modify/vary the amount of jojoba oil in the composition to achieve a desired result.

Regarding claims 32, Kawahara teaches in the examples containing tables 8, 10, 6, 11, 14, 15, 16, 17, 20 and 19 the use of preservatives in the compositions in amounts ranging from .1-.2%.

It would have been prima facie obvious to one of skill in the art to combine the teaching of Unger/Felke/Schmidt and Kawahara to arrive at the instant invention. One of skill in the art would have been motivated to substitute the galactocerebrosides taught by the combination of Felke/Unger/Schmidt with the glycosphingolipids taught by Kawahara to achieve an enhanced cosmetic, because as taught by Schmidt, galactocerebrosides are preferred glycolipids for use in cosmetics and Kawahara teaches the use of glycosphingolipids in combination with other ingredients to make cosmetics such as hand creams, lipstick and eye shadow preparations, eyeliner, cheek color and more. One of skill in the art would expect reasonable success because Felke/Unger/Schmidt and Kawahara all teach the use of sphingolipids, specifically glycosphingolipids in cosmetic/pharmaceutical compositions.

15. Claims 13 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,705,187, issued: 1/6/1998) and Felke et al (WO 95/20945, pub date: 2/16/1995), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998) as applied to claims 13-15 and 17-20 above, and further in view of Robbins et al (US 6,248,788, issued: 6/19/2001).

Unger/Felke/Schmidt teach all the limitations of claim 13, but fails to teach the limitations further recited by claims 24-25.

Robbins teaches the application of capsaicin in a concentration from about 5% to about 10%. This amount has been discovered to be an extremely effective therapy for treating neuropathic pain (Abstract). At present capsaicin is commercially available in over-the counter topical preparations at concentrations of 0.025% and 0.075% (Column 3, lines 15-20). The capsaicin containing composition is preferable administered topically and included a vehicle with skin penetrating properties, such as eucerin, a cosmetic skin lotion (Column 2, lines 15-20, 63-65). Considering that capsaicin can be found in quantities of 0.025-.075 and be given in quantities of up to 10%, it would have been obvious to one of skill in the art to optimize the quantity of capsaicin that should be incorporated into a cosmetic/pharmaceutical preparation, depending on the level of effect or results desired.

It would have been prima facie obvious to one of skill in the art at the time the invention was made to combine the teaching of Unger/Felke/Schmidt with those of Robbins to create a topical pharmaceutical composition or a cosmetic cream with pharmaceutical properties to provide the public with a composition effective at treating neuropathic pain. Finally one of skill would expect reasonable success because Unger/Felke/Schmidt teach that the lipid composition can contain bioactive agents, such as drugs and pharmaceuticals that can be applied topically.

16. Claims 13 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,705,187, issued: 1/6/1998) and Felke et al (WO 95/20945, pub date: 2/16/1995), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998) as

applied to claims 13-15 and 17-20 above, and further in view of Scivoletto (US 6,248,763, issued: 6/19/2001).

Unger/Felke/Schmidt teach all the limitations of claim 13, but fail to teach the limitations further recited by claims 26-27.

17. Scivoletto teaches a composition for skin treatment which include nicotinamide, nicotinic acid (elected species), also known as niacin, and nicotinic esters as active ingredients. The composition can be applied topically to the skin to treat skin conditions including acne, insect bites, bee stings, fungi, etc. Other intended used include makeup and lipstick (Abstract). The nicotinic acid can be combined with a variety of ingredients such as skin moisturizers, emollients, vitamin e, carrier and other beneficial elements (Column 1, lines 62-68). Some formulas are designed to dry quickly and clearly upon application. The formulas provide the user a smooth and even skin tone without the greasy, sticky finish or irritation caused by other skin care products. Nicotinic acid when combined with ingredients as those mentioned above have the surprising efficacy in treating various skin conditions. Niacin is found in amounts ranging from .01-1% by weight of the composition (Claims 1-2).

It would have been prima facie obvious to one of skill in the art at the time the invention was made to combine the teaching of Unger/Felke/Schmidt with those of Scivoletto to create a topical pharmaceutical composition or a cosmetic cream with pharmaceutical properties to provide the public with a composition effective at treating skin conditions such as acne, fine lines and much, much more. Finally one of skill would expect reasonable success because Unger/Felke/Schmidt teach that the lipid

composition can contain bioactive agents, such as drugs and pharmaceuticals that can be applied topically.

18. Claims 31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,705,187, issued: 1/6/1998) and Felke et al (WO 95/20945, pub date: 2/16/1995), cited on the 6/7/2006 IDS, Schmidt (US 5,776,470 issued: 7/7/1998) and Kawahara et al (US 2002/0037291, pub date: 3/28/2002)as applied to claims 13-15 and 17-23, 28-30 and 32 above, and further in view of Dawson et al (US 2002/0028182, pub date: 3/7/2002).

19. Unger/Felke/Schmidt/Kawahara teach all the limitations of claim of claims 31 and 33-36, but fail to teach the composition to comprise 1-3% polyethyleneglycol 75 shea butter glyceride, synonymous to Lipex 102 E-75, as demonstrated by Karlshamns Product Information, 15-25% by weight of 1,2-propylene glycol (propylene glycol) and qs water.

20. With respect to the quantity of propylene glycol, Kawahara teaches the use of 10% propylene glycol in a cosmetic composition, as such the difference between 10 and 15 is minimal and it would have been obvious to one of skill in the art to optimize the quantity of propylene glycol to reach the desired results. Kawahara also demonstrate various examples, such as Ex. 2-3, 6, 8-9, 11, 13-14, 16-19 which all comprise water in addition to the active ingredients, oil/wax, glycerin, propylene glycol and sphingolipids in quantities that complete the percentage of the composition to 100% after all the active

ingredients have been added, as such it is believed that the limitation recited "qs100% by weight water" is met.

21. Dawson teaches a personal cleansing product for the hair and skin (Abstract). The cleansing product can also comprise additional oil derived nonionic surfactants in quantities ranging from 0.1-20% (Pg 5 [0065]). Examples include jojoba oil, peanut oil, Lipex chemicals such as Lipex 102 E-75 and Lipex 102 E-3 (ethoxylated mono, di-glycerides of Shea Butter) (Pg 5 [0069-0070]). Highly preferred oil derived nonionic surfactants for use herein from the viewpoint of optimum mildness and skin feel characteristics are Lipex 102-E3, as such on of skill in the art could expect that Lipex 102 E-75 have similar characteristics to that of Lipex 102 E-3.

It would have been prima facie obvious to one of skill in the art to combine the teaching of Unger/Felke/Schmidt/Kawahara and Dawson to arrive at the instant invention. On of skill would have been motivated to add to the composition taught by Unger/Felke/Schmidt/Kawahara the polyethyleneglyol 75 shea butter glyceride taught by Dawson to incorporate skin feel characteristic into a cosmetic/pharmaceutical composition that can be applied topically. Finally one of skill would expect reasonable success because Unger/Felke/Schmidt/Kawahara teach that the lipid composition can contain bioactive agents, such as drugs and pharmaceuticals that can be applied topically.

## *Conclusion*

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JB

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615